

## Message

**From:** ets Personal Email / Ex. 6  
**Sent:** 5/16/2017 5:52:43 PM  
**To:** Clancy, Shaun Personal Email / Ex. 6  
**CC:** Henry, Tala [Henry.Tala@epa.gov]  
**Subject:** invitation to submit an abstract

Hi, Shaun:

It was nice meeting you at the Global Chem conf.

Tala Henry and I are cochairing a symposium "Implementation of TSCA as Amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act - Science Issues." The symposium is proposed for the next annual North America meeting of the Society of Environmental Toxicology and Chemistry. The meeting is planned for November 12-16 in Minneapolis-St. Paul. More information about the meeting can be found at <https://msp.setac.org>

We are inviting you to submit an abstract to the symposium. The description of the symposium follows. Abstracts can be submitted at <https://msp.setac.org/program/scientific-program/abstract-submission/> The abstract submission deadline is June 7.

Thank you for considering our symposium.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amends the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law was signed into law. The amended TSCA includes several new mandates, including: (1) a mandatory requirement for EPA to evaluate existing chemicals with clear and enforceable deadlines; (2) a new risk-based safety standard for both new and existing chemicals; (3) increased public transparency for chemical information; and (4) a consistent source of funding for EPA to carry out the responsibilities under the new law. Several of the new provisions of TSCA require additional science-based approaches to be developed, advanced and/or applied. Under section 4 of TSCA, EPA must reduce and replace, to the extent practicable, and must encourage and facilitate the use of scientifically valid test methods and strategies that will support regulatory decisions. Under section 5 of TSCA, EPA must make an affirmative finding with regard to unreasonable risk, often with very limited information available, which requires application of predictive models and estimation approaches and/or requests for testing when information is insufficient to make a reasoned evaluation. Section 6 of TSCA requires that EPA develop a risk-based screening process to identify high-priority and low-priority chemicals for further risk evaluation. This prioritization process must include considerations of hazard, exposure potential, persistence and bioaccumulation among other things. Risk evaluation must be conducted for all chemicals designated high-priority and must integrate and assess available information on hazards and exposures for the conditions of use of a chemical substance. Furthermore, EPA must also apply a number of scientific standards in carrying out sections 4, 5 and 6 of TSCA, including to use scientific information in a manner consistent with the best available science and consider as applicable reasonableness, relevance, clarity and completeness, variability and uncertainty, and peer review. In the interest of facilitating a scientific discussion and dialog regarding scientific approaches, databases, tools & models that may be brought to bear in implementing amended TSCA, we are seeking presentations on the following topics, particularly as they are available or apply to ecological receptors and ecosystems: alternatives to vertebrate testing and species extrapolation tools/models; tiered testing schemes for ecological systems; predictive tools such as (Q)SARs, expert systems, and analog identification techniques; and systematic review approaches - especially including reliability and relevance considerations and weight-of-evidence approaches.

stuart

Stuart Z. Cohen, Ph.D., CGWP  
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-----Original Message-----

From: Clancy, Shaun <**Personal Email / Ex. 6**>  
To: ets <**Personal Email / Ex. 6**>  
Subject: RE: nanomaterials, TSCA, and FIFRA  
Sent: Feb 16 '17 4:35pm

I'm not always so responsive so please don't get used to it. ;-) Thanks for the pic and the presentation. I was just on an RCC call with Tala a little while ago. I will be looking for you next week.

**Shaun F. Clancy, Ph.D.**

Director of Product Stewardship

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**From:** ets [mailto: Personal Email / Ex. 6]  
**Sent:** Thursday, February 16, 2017 3:30 PM  
**To:** Clancy, Shaun < Personal Email / Ex. 6 >  
**Subject:** RE: nanomaterials, TSCA, and FIFRA

Hi, Shaun:

That was very nice of you to respond so quickly.

Yes, I was working with the Uniroyal side of Crompton.

FYI: Tala Henry (EPA) and I have tentative plans to submit a proposal to run a TSCA symposium at the next SETAC North America mtg in Minneapolis in November. I plan to keep you informed.

Regarding the PMN submissions: We use structural analog and QSAR information, coupled with high throughput screening data and water quality modeling expertise, among other factors. Regarding QSAR, I ran a symposium on QSAR at the last Am. Chem. Soc. mtg, and I have att'd my presentation, which was the kickoff paper for the symposium. We had four or five speakers from the EPA.

I hope to meet you next week. I have att'd a photo, so you could spot me in the crowd.

Thanks again for your time. I know you are very busy.

stuart

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-----Original Message-----

From: Clancy, Shaun <Personal Email / Ex. 6>

To: ets <Personal Email / Ex. 6>

Subject: RE: nanomaterials, TSCA, and FIFRA

Sent: Feb 16 '17 1:56pm

Hi Stuart,

I don't recall meeting during my Crompton/Witco days but it's possible we crossed paths. Do you remember who you worked with? If you were dealing with people such as Alan Taylor or Joe Lomenzo then you were dealing with the Crompton & Knowles/Uniroyal businesses. I don't recognize Mark or Betsy. I came from the Witco side. Your name is familiar to me via the emails I've seen from the SETAC TSCA group.

Regarding the unique nano properties, we have not seen anything definitive on what it means to be unique. We have had a lot of discussion with various regulators on the issues and appreciate that it's difficult for them to be clear since they rely in part on the intent. It's not an easy question.

I will keep you mind for TSCA and FIFRA. I'm personally very active in TSCA discussions directly with EPA on behalf of Evonik and also through associations. A big concern for me is how slow PMN reviews are right now. We generally keep this work in house but it's good to know there are other resources we can call on. Evonik has limited FIFRA work that is also managed in house but again, knowing about other resources is helpful. I will be at GlobalChem next week and expect to cross paths there.

Shaun

**Shaun F. Clancy, Ph.D.**

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**From:** ets Personal Email / Ex. 6  
**Sent:** Thursday, February 16, 2017 1:15 PM  
**To:** Clancy, Shaun Personal Email / Ex. 6  
**Subject:** nanomaterials, TSCA, and FIFRA

Hi, Dr. Clancy:

I am not sure we met when we were a consultant to Crompton, so please allow me to introduce my firm. We are a small, environmental consulting firm -- Environmental & Turf Services, Inc. -- that specializes in environmental chemistry and risk assessments under FIFRA, TSCA section 5 (PMNs) presubmission risk screening, and environmental risk assessment and management for golf courses.

**Nanomaterials:** I read with interest your paper, "Comparative Assessment of Nanomaterial Definitions and Safety Evaluation Considerations" (2015). Good work. Of course, one of the key science questions was in your example approach (Figure 4), "Does the nanomaterial have novel size-dependent properties relative to larger forms of the same material?" Were you successful in initiating a regulatory dialog on the governmental inconsistencies you found?

**TSCA:** Please consider using our firm for TSCA PMN presubmission risk screening. The purpose of this task is to steer EPA scientists away from the overly conservative approach they have been taking since TSCA was reformed June 22. I can provide much more information on the cost and methods we provide for this service if you or one of your staff is interested. FYI: In one of my positions in 11 yrs with the US EPA, I was the first staff employee hired in the Premanufacture Notification Div. More recently, I was involved with briefing Congress and staff on risk assessment science, during the rewrite of TSCA, in my role as chair of the TSCA Reform Dialog Group of the Society of Environmental Toxicology and Chemistry.

**FIFRA:** I don't know about Evonik's involvement with FIFRA, but we support registrants on environmental fate and risk assessment issues in their interactions with the EPA. (I worked in the former/old Hazard Evaluation Division in OPP.) We were Crompton's key consultant on PCNB. At that time, we interacted with Mark Shocken and Betsy Katzen(?).

I would be happy to discuss with you or your staff further how we might assist Evonik with regulatory compliance, either by phone, email, in your office, or at the Global Chem meeting next week in Washington, D.C.

I know you are extremely busy. Thank you for taking the time to read my note.

P.S. Congratulations on being named company of the year! What an honor.

stuart

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